DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

November 13, 2000

CIN-XR-5199-0
REFERENCED TEST NO.: GI -64239

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jeffrey Mangione
President
Precise Biomedical Inc.
2147 Broadview Rd.
Cleveland, OH 44109

Dear Mr. Mangione:

On September 7, 2000, a representative of the FDA under the partnership with the State of Ohio performed a field test of a certified diagnostic x-ray system that your firm assembled on January 12, 2000. We received a notice of the assembly on Form FDA 2579, Assembler Report No. D284065 (Report of Assembly of a Diagnostic X-Ray System). We tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-Ray Equipment (Title 21 Code of Federal Regulations (CFR), sections 1020.30-32). Diagnostic x-ray equipment are devices as defined by section 201 (h) of the Federal Food, Drug and Cosmetic Act (the Act). This field test was performed at:

Oberlin Avenue Medical Center
5373 Oberlin Ave.
Lorain, OH 44053

System identification:

X-Ray Control Manufacturer: Picker International
X-Ray Control Model No.: 755-270-E
X-Ray Control Serial No.: 1569X
Room Number: R& F Room

Our analysis of the field test data indicates that the system does not comply with the following items of the performance standard:

Radiographic mode

The equipment is originally designed to operate with positive beam limitation (PBL). During the survey no form of positive beam limitation was observed to the x-ray table and to the vertical cassette holder.

The Performance Standard requires that PBL shall be provided as the intended design of the diagnostic x-ray system. **[21 CFR 1020.31 (g)(1)-(5)]**

Fluoroscopic Portion:

Spot Film Reproducibility

The survey found coefficient of variation = 0.069 after a sample set of ten exposures at 100 kVp, 100 mA in the phototimer mode.

The Performance Standard requires that "For any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposures shall not exceed 0.05. **[21 CFR 1020.31(b)(1)&(2)]**

In addition to the above problems, we consider the compliance status of the following item to be suspect. Please verify the compliance status of this item when you correct the previously cited problems.

Radiographic mode

Accuracy of Indicated Source to Image Receptor Distance (SID)

Indicated SID = 86.4 cm (34 inches)
Measured SID = 88.1 cm
SID difference = minus 2.01%

The Performance Standard requires that the x-ray system indicate the SID to within two (2) percent. **21 CFR 1020.31 (e)(1)**

We request that you, as the responsible assembler, immediately investigate the deviations from the performance standard cited above in accordance with 21 CFR 1003 and 1004 as follows:

1. If you determine that the deviations and/or defects are caused by improper assembly or installation, you must correct the noncompliance items at no charge to the user by repairing the system, replacing it or refunding the cost.

2. If you determine that the deviations are caused by the factory-based manufacturer, you must notify him of the noncompliance items and/or defects and send documentation of notification to this office.

3. If you can establish that the system is compliant, that the alleged deviations or defects do not exist or do not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence in accordance with 21 CFR 1003.30 within 30 working days of receipt of this letter.

You must report the results of your investigation and follow-up to this office within 30 working days of receipt of this letter. Your response should include the date the corrective action was completed and copies of service records and/or other supportive documents. If you do not respond within 30 working days, the FDA may consider you to be in violation of the Federal Food, Drug and Cosmetic Act (the Act), sections 538(a)(2) and 538(a)(4) of Subchapter C-Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Please note that improper installation, including failure to follow installation instructions that cause the system to be noncompliant with the Performance Standard may cause the system to be adulterated. Under 501(c) of the Act, the system would not be of a quality represented by the labeling (including the certification statement).

Failure to promptly correct these violations can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of the civil penalties as provided for in section 539 of the Act. Persons violating section 538 of the Act are subject to civil penalties of up to $1000 per violation and up to a maximum of $300,000.

You should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to Mr. R. Terry Bolen, Radiological Health Specialist, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237-3097.

If you have any questions, Mr. R. Terry Bolen can be contacted at 513-679-2700, extension 138.

Sincerely,

Deborah A. Grelle
Director of Compliance
Cincinnati District

c.
M.Dixon, RT
Oberlin Avenue Medical Center
5373 Oberlin Ave.
Lorain, OH 44053